

IN THE SUPREME COURT OF THE STATE OF MONTANA
Supreme Court Cause No. DA-10-0029

PEGGY STEVENS,
Plaintiff/Appellee/Cross Appellant

v.

NOVARTIS PHARMACEUTICALS CORPORATION,
Defendant/Appellant/Cross Appellee

BRIEF OF APPELLEE/CROSS-APPELLANT, PEGGY STEVENS

**ON APPEAL FROM THE FOURTH JUDICIAL DISTRICT COURT
MISSOULA COUNTY, THE HONORABLE JOHN LARSON PRESIDING**

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Statement of Issues

Direct Appeal

1) Did the district court correctly decide, as a matter of law based on the uncontroverted evidence, that Novartis Pharmaceutical Corporation was timely sued by a fictitious name and timely substituted when Peggy Stevens first became aware of its culpability for her injuries?

2) Would the results have been the same based on the fact that the statute of limitations was tolled from September 15, 2005, to November 14, 2007, by a pending class action in which identical relief was sought?

3) Did the district court err by instructing the jury that a drug manufacturer has a duty to provide adequate warnings to healthcare providers who are in a position to reduce the risk of harm to those who are treated with the manufacturer's drugs?

4) Did the district court abuse its discretion by refusing to permit NPC to cross examine a lay witness with prior pleadings, discovery, and unsworn, out-of-court summaries of expert opinions which she had not prepared and about which she was unqualified to comment?

5) Did the district court abuse its discretion when it refused to allow NPC to amend its answer shortly before trial to place blame on a dismissed defendant after it repeatedly refused to answer written discovery asking whether it

intended to do so?

6) Was there sufficient evidence of causation when it was proven that for lack of knowledge about the danger, Guardian Oncology professional staff had no protocol for advising patients about the risk of osteonecrosis of the jaw from tooth extractions while being treated with Zometa, where it was proven that Peggy Stevens had alternatives to a tooth extraction for treatment of her fractured tooth, and where expert testimony clearly established that plaintiff's ONJ resulted from her tooth extraction?

7) After NPC repeatedly argued that Peggy Stevens could not prove causation because the office of her oncologist would not have passed along warnings to her even if they had been warned, did the district court abuse its discretion by allowing the office manager to testify that when finally informed of the risk of osteonecrosis, she established a protocol for warning all patients?

Cross Appeal

1) Did the district court abuse its discretion when it refused to allow Peggy Stevens to amend her complaint to claim punitive damages?

2) Did the district court err when it dismissed Ms. Stevens claim that Patrick Doyle, NPC's sales representative, was negligent based on its conclusion that because he acted in the course of his employment, he had no individual liability?

3) Did the district court err by offsetting disability benefits from a general verdict which did not specify the types of damages awarded and potential future benefits even though the offset statute pertains only to those benefits received?

Statement of the Case

On January 18, 2008, Peggy Stevens filed a complaint in the district court in which she alleged that after being diagnosed with follicular lymphoma in October, 2000, she was treated with Zometa from April of 2002 through March of 2005 (Doc. 1, ¶¶ 5, 6). She alleged that on September 27, 2004, she had a tooth extracted by Dr. Eugene Morris after which she developed mandibular pain which was diagnosed as osteonecrosis of her right mandible (ONJ) on March 18, 2005 (¶¶8, 9, and 10). She alleged that Judy Schmidt, MD, and Guardian Oncology which employed her were negligent for failing to advise her of the need to avoid tooth extractions while being treated with Zometa and that that negligence was the cause of her ONJ and resulting damages. (¶¶11, 12, 16 and 18)

The complaint named as defendants, “John Does 1 through 5” and alleged that they were other individuals or entities whose conduct may have contributed to plaintiff’s injuries but who were then unknown to the plaintiff. (¶4)

On January 13, 2009, Ms. Stevens amended her complaint to substitute Patrick Doyle and Novartis Pharmaceuticals Corporation for John Does 1 and 2 and added an alternative allegation that if Doyle and NPC had not provided timely notice to Schmidt or Guardian Oncology about the potential for ONJ from a tooth extraction while being treated with Zometa, then the substituted defendants were negligent and were the cause of her injury. (Doc. 58, ¶20)

On February 26, 2009, Doyle moved to dismiss (Doc. 85) based on his contention that because his conduct was imputed to his employer he could not be liable in his individual capacity. (Doc. 86)

On April 7, 2009, the district court granted Doyle's motion. (Doc. 125, pp. 6, 7, and 8; App. 1)

On May 20, 2009, at NPC's insistence, the district court entered a protective and confidentiality order (Doc. 148; App. 2) which allowed Ms. Stevens to gather information from third parties that NPC had refused to provide in response to written discovery.

Having received no response to discovery suggesting that NPC would blame any third party, the court and parties were given notice on June 12, 2009, of Ms. Stevens' settlement with Judy Schmidt and Guardian Oncology (Doc. 170). On July 8, 2009, those defendants were dismissed with prejudice (Doc. 183.1).

On July 15, 2009, the trial date was continued for a second time at NPC's request. This time to October 13, 2009 (Doc. 191). Eight days later, based on information discovered from third parties as a result of the district court's confidentiality order, Ms. Stevens filed a motion to file a second amended complaint, expanding the class of people to whom Novartis owed notice to include her treating physicians, including her oral surgeon, and to allege a claim for punitive damages pursuant to §27-1-221. (Doc. 193, Exh. 1, pp. 7 and 8)

On August 4, 2009, after Dr. Schmidt and Guardian Oncology had been released and had no incentive to incur the expense of a defense and in spite of its previous refusal to answer discovery about its intention to do so, NPC moved to amend its answer to blame them for Peggy Stevens' injuries and thereby reduce its own liability pursuant to §27-1-703(6)(f). (Doc. 211)

On September 14, 2009, the district court denied plaintiff's motion to file a second amended complaint based on its conclusion that the limited time remaining before trial would cause undue delay in the litigation. (Doc. 311, p. 7; App. 3) On September 16, 2009, the district court denied NPC's motion to amend its answer based on its conclusion that it did not act with reasonable promptness following notice of Dr. Schmidt's release on June 12, 2009, as required by §27-1-703(6)(f). (Doc. 324, pp. 5 and 6; App. 4)

On September 14, 2009, NPC had filed a reply brief in support of its third motion to continue the trial date, contending that there was "much that is still to be done," and that it would be prejudiced if the continuance was not allowed. (Doc. 317, pp. 3, 4)

Two days later, Ms. Stevens filed an amended motion to file her second amended complaint and agreed that the trial date could be continued. (Doc. 326) In response, on September 17, 2009, three days after the reply brief in support of its motion to continue, Novartis refused to agree to the stipulation to continue,

withdrew its motion to continue and stated that it had resolved the problems that made a continuance necessary. (Doc. 331, pp. 4 and 5) On September 21, 2009, the plaintiff's amended motion to file its second amended complaint was denied. (Doc. 336, pp. 3 and 4; App. 5)

The pre-trial order was filed on October 5, 2009. (Doc. 384) Among NPC's contentions were allegations that even if Dr. Schmidt's office had known about the risk of ONJ from a tooth extraction, it would not have passed that information on to Peggy Stevens (p. 10, ¶10) and that Peggy Stevens had no alternative but to undergo invasive dental surgery, and therefore, its failure to warn was not the cause of her injuries (p. 10, ¶9).

This case went to trial on October 13, 2009. The jury returned its verdict on October 21, 2009. (Doc. 418.6; App. 6) The first question to the jury was whether NPC was negligent "in its label or information to Dr. Judy Schmidt or Guardian Oncology treating professional staff (but no other healthcare provider) about Zometa prior to September 27, 2004?" The jury was instructed that if their answer to that question was "No" they should not go further. They answered the question "Yes." The jury found that Ms. Stevens had been damaged in the amount of \$3,200,000. That amount was subsequently reduced by the district court to \$2,659,257.32 after the addition of expenses and offset for the prior settlement with Dr. Schmidt, short-term disability benefits received, and Social Security

benefits. (Doc. 486, pp. 3, 4, 7-9, and 12; App. 7)

Statement of Facts

Introduction

Zometa is the brand name for a zoledronic acid drug manufactured by NPC. It belongs to a class of drugs known as bisphosphonates. (Tr. 806) In approximately February, 2002, it was approved by the FDA for treatment of bone metastasis of solid tumors. (Tr. 1076)

Bisphosphonates kill a cell called an osteoclast which recognizes old and dying bone and dissolves it, allowing bone to renew itself and permit bone growth. (Tr. 759-761) In that manner, Zometa achieves its therapeutic effect (preventing fractures) by hardening the bone thereby preventing cancer from eating away at the bone. However, it concentrates in the jaws. When it interrupts osteoclast activity it prevents bone renewal, and if the dosage is sufficient, the bone dies off – especially around the areas around the teeth. (Tr. 761) This condition is known as bisphosphonate-induced osteonecrosis of the jaw (BIONJ). (Tr. 761) Osteonecrosis means dead bone. (Tr. 738)

Remodeling is even more critical after a tooth is extracted or when the jawbone is injured. A jawbone that cannot remodel in response to trauma is more vulnerable to bone death. (Tr. 762, 763)

Testimony of Robert Marx, D.D.S.

Dr. Marx is an oral and maxillofacial surgeon at the University of Miami, School of Medicine. (Tr. 734) His emphasis is on bone pathology or diseases of the bone. (Tr. 737)

Dr. Marx has published articles and textbooks on the subject of BIONJ. (Tr. 742) He was considered by Peggy's Missoula dentist and oral surgeon to be the leading authority in the country on the topic of BIONJ. (Tr. 574 and 666)

In 2003, Dr. Marx published an article in the Journal of Oral and Maxillofacial Surgery described as a "Medical Alert" describing 36 patients he had seen with exposed jawbone directly linked to intravenous bisphosphonates and described it as a "growing epidemic." (Tr. 748, 749)

Armed with this experience, he contacted NPC in 2003 and advised it of the strong association with their medication, including Zometa. (Tr. 764) In response, he was invited by NPC to a December 5, 2003, meeting to discuss the issue. (Tr. 764-766) Also in attendance, was Dr. Salvatore Ruggiero who by then had published an article identifying 63 cases of BIONJ. (Tr. 766)

Dr. Marx explained to NPC his belief that there was a direct cause and effect relationship between bisphosphonates and ONJ. (Tr. 766)

Following the initial meeting, Drs. Marx, Ruggiero and other specialists were invited by Novartis to a second meeting in April of 2004, the objective of

which was to produce recommendations for prevention and treatment of ONJ, known as a “white paper.” (Tr. 766, 767) The paper was ghost-written by someone at NPC. (Tr. 820) After it was circulated, Drs. Ruggiero and Marx and other panel members expressed disappointment because of the paper’s attempt to ascribe causation to a number of other factors, including chemotherapy and smoking, which had no direct relationship to ONJ. (Tr. 767, 768, 1606, 1607) Dr. Marx also criticized the paper’s failure to acknowledge the direct causal relationship between bisphosphonate therapy and ONJ and submitted proposed revisions to the paper which were ignored by NPC’s director of research. (Tr. 768) After his criticism, Dr. Marx was not invited to attend any more meetings of Novartis’ advisory boards. (Tr. 769)

By the time of trial, Dr. Marx had seen and attempted to treat 211 cases of BIONJ. (Tr. 1621) However, there is no cure. (Tr. 801, 802) It is managed with antiseptic mouthwash and antibiotics or amputation of the jaw. (Tr. 741) It is also characterized by chronic pain and infection. (Tr. 801)

Exh. 515 was the “white paper” entitled “Recommendations for the Prevention, Diagnosis, and Treatment of Osteonecrosis of Jaws.” It was published in June of 2004. (Tr. 815-817) Exh. 693 was the Zometa “label” or package insert provided by NPC in the drug package. (Tr. 802, 803) Both list “multiple recognized conditions and risk factors associated with the development of [ONJ]”

(Tr. 826) and both state that “a causal relationship between bisphosphonate therapy and [ONJ] has not been established.” (Tr. 827)

Dr. Marx testified that there is no causal relationship between the other alleged risk factors and ONJ. (Tr. 1609-1619) Dr. Marx expressed the opinion to a reasonable degree of medical certainty that Zometa does cause ONJ. (Tr. 759)

Testimony of Suzanne Parisian, M.D.

Dr. Suzanne Parisian is a board-certified pathologist and former medical officer at the US Food and Drug Administration. (Tr. 1045) She has authored a book entitled, “FDA Inside And Out” which is currently used as a textbook at at least two universities. (Tr. 1055, 1056)

In response to NPC’s defense that its drug and the label or warning that came with it had been approved by the FDA, she explained that the FDA doesn’t do its own testing but relies on testing done by the manufacturer in support of an application for approval. (Tr. 1054)

Dr. Parisian testified that after reviewing company documents, deposition testimony in related cases, and more research than had been provided to the FDA (Tr. 1068-1070), the information provided on the label about ONJ was not reasonable (Tr. 1097) and that NPC did an inadequate job of monitoring the causal relationship between Zometa and ONJ. (Tr. 1150)

Testimony of Peggy Stevens

Peggy Stevens was diagnosed with follicular lymphoma in 2000 and referred to Dr. Judy Schmidt, an oncologist. (Tr. 470) She began taking Zometa in April of 2002 for bone metastasis and received it until sometime in 2005.

In 2004, she was told that she needed a crown on the last tooth in her right mandible because the tooth was cracked. (Tr. 479, 480) She couldn't afford to have it crowned and decided to have it pulled by Dr. Morris, an oral and maxillofacial surgeon. (Tr. 480, 481)

During the two months prior to her September 27, 2004, tooth extraction, she was still a patient in Dr. Schmidt's office but most of her interaction was with the nurses and visiting physicians. She had no interaction with Dr. Schmidt other than to say hello in the hallway. (Tr. 481, 482)

She advised the nurses and one of the visiting physicians that she was having a tooth extracted. (Tr. 482) No one advised against it. (Tr. 482) Nor did Dr. Morris mention anything about the risk of ONJ. (Tr. 483)

Following the tooth removal, Peggy experienced increased pain which continued to worsen. (Tr. 483, 484) Following tests, she was told that she had ONJ from the extraction. (Tr. 484, 485)

Peggy has been treated with narcotics for pain, antibiotics and antiseptic mouthwashes. (Tr. 486, 487) However, she has been advised that there is no

effective treatment, that the condition is progressive, and that the bone will continue to die. (Tr. 487, 488) The area of dead bone is larger than when first discovered, the gum has detached from the bone around that area, there is infection under the gum and she has constant drainage of pus. (Tr. 488)

She has been cancer-free since 2005 (Tr. 498), but had to leave her \$70,000 per year job as a health supervisor at Community Medical Center in March of 2007 because the pain became so severe she could no longer perform her duties (Tr. 463-465) and because of the hospital's zero tolerance for narcotics. (Tr. 492, 493) Before then, she had worked as a nurse for 33 years. (Tr. 466) She was 57 years old at the time of trial. (Tr. 463)

Peggy testified that had she known there was an increased risk from tooth extraction and that there was an alternative, she would not have had the extraction. (Tr. 485)

Testimony of Judy Schmidt, M.D.

Dr. Judy Schmidt testified that as far as she knew from the information she had been able to gather prior to Peggy's tooth extraction, there had been no clear association made between Zometa and ONJ. (Tr. 1377) She noted that the March 2004 label stated that "causality" for ONJ "cannot be determined" (Tr. 1383) and that NPC's highly-touted "white paper" stated "the precise risk factors for [ONJ] have not been identified." (Tr. 1388)

On two previous occasions, she had submitted adverse event reports to Novartis about ONJ and Zometa patients. (Tr. 1407-1408) Exh. 299 was a letter she received from Novartis after reporting a previous case of ONJ. It is dated December 10, 2003, and stated “it is not clear at this time whether there is any causal association between bisphosphonates and osteonecrosis or what the scientific basis is for such an association, if it exists.” (Tr. 1426-1428) At no time did Novartis, in response to her questions, advise her there was a relationship between jaw problems and patients taking Zometa. (Tr. 1429)

She did not know when she received the white paper (Tr. 1415) but stated she did not have it when Peggy Stevens had her tooth pulled (Tr. 1415, 1416), nor did she think that a patient had to be advised of a “possible association” between a risk and a medication. (Tr. 1414)

She stated that she was not aware in August of 2004 that the majority of ONJ cases had been associated with dental procedures such as tooth extractions (Tr. 1422, 1423), but in her deposition testified that had she been aware of it, she would have felt an obligation to advise Peggy. (Tr. 1423, 1424)

NPC’s Statement of Facts

It is not correct as suggested on p. 9 of NPC’s brief that Peggy Stevens was aware of the facts constituting her claim against NPC prior to filing her original complaint. In fact, the whole basis for her original complaint was her assumption

that her healthcare providers had been adequately warned about the risk of ONJ and had not passed that information along to her. She subsequently learned that they had not been adequately warned and that is the nature of her complaint against NPC. Nor were she or her attorney aware that NPC may not even have effectively communicated the minimal information buried in its “white paper” and label to Peggy’s healthcare providers.

On p. 10 of its brief, NPC suggests that Peggy knew about Novartis culpability because prior to filing her original complaint, she had seen its September 24, 2004, “Dear Doctor” letter (warning of ONJ) which was sent to oncologists sometime after her tooth extraction. However, knowing about the letter would only have reinforced to Peggy Stevens that her doctor had in fact been warned prior to her tooth extraction. It was only after the litigation commenced that she learned that the “Dear Doctor” letter had not even been sent to Judy Schmidt prior to her tooth extraction and that a “Dear Doctor” letter hadn’t been sent to dentists and oral surgeons until 2005.

ARGUMENT

I. STATUTE OF LIMITATIONS

STANDARD OF REVIEW

Legal issues are reviewed de novo. *Tucker v. Farmers Ins. Exch.*, 2009 MT 247, ¶23, 351 Mont. 448, 215 P.3d 1.

SUMMARY OF ARGUMENT

A. NPC was properly substituted for a John Doe defendant named in a timely complaint as soon as reasonably possible after plaintiff became aware of its connection to her injuries. Therefore, plaintiff's claim is not barred by the statute of limitations.

B. The statute of limitations was tolled during the pendency of previous putative class actions which asserted the same claim against the same defendant. After calculating the tolled time period, Peggy Stevens' complaint was filed well within the time allowed.

DISCUSSION

Plaintiff's complaint was filed on January 17, 2008, well within the three-year statute of limitations which NPC contends commenced to run on March 18, 2005. As previously noted, John Does I through IV were named in the complaint as others, whose conduct may have contributed to Peggy Stevens' injuries.

Accompanying Ms. Stevens' September 28, 2009, brief filed in opposition to NPC's Motion for Summary Judgment was the affidavit of her attorney. (Doc. 350, Exh. 2) It is attached hereto as App. 8. It was not contradicted.

It established that before the original action was commenced he was aware of the recommendations and the “white paper” published in June of 2004, and knew that Judy Schmidt had received those recommendations from her drug representative, did not know when they were delivered but assumed they had been delivered prior to the tooth extraction since they were dated June 2004. (¶¶1-4)

It established that he learned of the drug representative’s name and whereabouts by October 29, 2008, and was first allowed to question him on December 8, 2008, which is when plaintiff first learned that Doyle didn’t know when the recommendations had been delivered. (¶¶5 and 6)

It established that even after Novartis was named in this case, it refused to respond to written discovery, identifying prior claims or explaining the nature of those claims, and that it wasn’t until May 20, 2009, that Peggy’s attorney, with the assistance of other attorneys around the country, learned that even the “white paper” disseminated by NPC was not an accurate representation of what the experts it consulted had concluded and was in fact misleading by understating what NPC actually knew about the causal relationship between its drugs and ONJ. (¶ 7)

Based on the undisputed affidavit, verified by deposition testimony¹, and the law which follows, Peggy Stevens was entitled to judgment as a matter of law on the statute of limitations issue.

¹ See Schmidt depo, 132:7-16, App. 9; Landes depo. 9:7-10, 10:5-11:14, App. 10; Berenson depo, 44:24-45:6, App. 11; and Doyle depo, 31:12-18, 32:3-33:6, App. 12.

Montana's fictitious defendants statute, found in §25-5-103 MCA, allows a plaintiff to name fictitious defendants and amend his or her complaint at a later date to substitute actual defendants as long as done within 3 years of the original complaint. It's no more prejudicial to NPC than would be Rule 4E M.R.Civ.P. which allows a plaintiff to defer service of process for 3 years after filing a complaint. The complaint against the substituted defendant relates back to the original complaint. (See *Molina v. Pinko Constr., Inc.*, 2004 MT198, 322, Mont. 268, 95 P.3rd 687. The fictitious defendant statute is to be liberally construed. *Molina* ¶¶7-8)

NPC contends that the statute is not applicable because plaintiff was aware prior to her original complaint that it was the manufacturer of Zometa and that there was a possible connection between Zometa and her ONJ. However, it is not her contention that she was injured simply because she was treated with Zometa. Her contention is that she developed ONJ because while being treated with Zometa she had her tooth extracted without prior warning that a tooth extraction can cause ONJ in a Zometa patient.

Therefore, based on the following authorities, the fact that she knew Zometa was manufactured by NPC and that Zometa contributed to the cause of her ONJ is irrelevant to whether NPC is a properly substituted John Doe defendant.

While there is no authority from this court directly on point, California's

fictitious name statute, *Cal Code Civ Proc* §474 (2008), is similarly applicable to situations “when the plaintiff is ignorant of the name of the defendant,” and therefore this court has, in the past, looked to California’s interpretations of that statute for guidance. See *Sooy v. Petrolane Steel Gas, Inc.*, 218 Mont. 418, 708 P.2nd 1014 (1985).

Based on California’s interpretation of the same language, it is well established “that even though a plaintiff knows of the existence of the defendants sued by a fictitious name, and even though the plaintiff knows the defendant’s actual identity, the plaintiff is ‘ignorant’ within the meaning of the statute if he lacks knowledge of that person’s connection with the case or his ‘injuries’ at the time the original complaint was filed. *GM Corp. v. Superior Court*, 48 Cal. App. 4th 580, 593-594 (Cal. App. 4th Dist. 1996); *Dover v. Sadowlinski*, 147 Cal. App. 3rd 113, 194 (Cal. App. 2nd Dist. 1983) (Plaintiff was deemed “ignorant of the name” if he knew the identify of the person but was ignorant of the facts giving him a cause of action against the person.); See also *Lindley v. General Electric Co.*, 780 F.2d 797 (9th Cir. Cal. 1986).

In fact, in *Molina*, this court cited *GM Corp. v. Superior Court, Supra*, for the principle that “California has long held that the fictitious name statute should be liberally construed.” *Molina*, ¶8.

See also *McOwen v. Grossman*, 153 Cal. App. 4th 937, 63 Cal. Rptr. 3d 615 (2007 Cal. App.), where the court stated :

“The phrase ‘ignorant of the name of a defendant is broadly interpreted to mean not only ignorant of the defendant’s identity, but also ignorant of the facts giving rise to a cause of action against that defendant.’” (citations omitted) *McOwen*, 63 Cal. Rptr. 3rd at 620

In addition to California, Alabama and Mississippi follow the same rule. See *Womble v. Singing River Hosp.*, 618 So. 2d 1252, 1266-68 (Miss. 1993) and *Dannelley v. Guarino*, 472 So. 2d 983, 986 (Ala. 1985).

To require that NPC be named before there is a factual basis for doing so would encourage baseless lawsuits, would bring further criticism of the civil justice system, would, therefore, be bad policy, and would be contrary to the liberal construction of the fictitious defendants statute required by this court’s prior decisions.

On pp. 20 and 21 of its brief, NPC cites extensively from the non-binding decision of another state district court in the case of *Franchi v. City of Helena*, No. BDV-04-262, 2005 Mont. Dist. LEXIS 529 (Mont. Dist. Ct., Mar. 16, 2005). However, that order is very brief, did not cite the controlling case law which was brought to this district court’s attention, and it is not known what law was cited to that court. No authority for its decision is given by the court and the opinion is, therefore, unpersuasive.

On p. 21 of its brief, Novartis' mischaracterizes the easily distinguished case of *Dover v. Sadowinski*, 147 Cal. App. 3d 113 (Cal. App. 2d Dist. 1983). The rule re-affirmed in that case was--"[t]he plaintiff is deemed 'ignorant of the name' if he knew the identity of the person but was ignorant of facts giving him a cause of action against the person." *Dover*, 147 Cal. App. 3d at 116 (citation omitted). However, the court in applying this rule found that the plaintiff was not ignorant of defendant's identity or the facts giving rise to the wrongful death cause of action.

On pp. 17 and 18 of its brief, NPC discusses the "discovery rule" as it applies to the timeliness of lawsuits in Montana. However, neither of the cases cited were decided in the context of the fictitious defendant statute. And, therefore, they are inapplicable to this case. Additionally, the court in *Bennett v. Dowe Chem. Co.*, 220 Mont., 117, 121, 713 P.2d 992, 994-95 (1986) noted that "application of the general [discovery] rule becomes difficult when the injured person is prevented from knowing of his injury by concealment or other circumstances" and declared that "a statute of limitations can be tolled until a plaintiff discovers the legal cause of his injury if equity so dictates." *Bennett*, 220 Mont. at 121, 713 P. 2d at 995.

In footnotes on pp. 21 and 22 of its brief, NPC cites unpublished California decisions to suggest that the rule relied on by Peggy Stevens and the district court is no longer the rule in California. However, that is incorrect. The rule remains

the same. The cases cited are distinguishable on their facts and do not overrule any previous authority.

Finally Novartis contends on p. 24 of its brief that there was still an issue of fact about whether the plaintiff's complaint was timely and that it should have been decided by the jury. It faults the court for refusing jury instructions proposed by Novartis which misstated the law. However, the statute of limitations is an affirmative defense. See *John R. Sand and Gravel Co. v. United States*, 552 U.S. 130, 133 (2008). A defendant bears the burden of proof in asserting an affirmative defense. *Wareing v. Schreckendgust*, 280 Mont. 196, 212, 930 P.2d 37, 46 (1996) "[A] district court does not need to instruct [the jury] on a theory unless there is evidence to support the theory." *Howard v. St. James County Hosp.*, 2006, MT 23, ¶26, 331 Mont. 60, 129 P.3d 126 (citing *Edie v. Gray*, 2005 MT 224, ¶21, 328 Mont. 354, 121 P.3d 516). If there is no conflict in the evidence, a district court does not err if it refuses to instruct the jury regarding a statute of limitations defense. See *Cechovic v. Hardin and Assoc.*, 273 Mont. 104, 119, 902 P.2d 520, 529 (1995).

At trial, the only testimony regarding the statute of limitations was given by Peggy Stevens who, when asked at Tr. 485 whether when her original complaint was filed she had any idea what Novartis knew about the risk of ONJ, answered that she did not. At Tr. 1028-1029 she stated that she had no understanding of the

extent of Novartis' knowledge about Zometa's causal relationship to ONJ before her claim against Novartis was actually brought. Novartis offered no evidence to the contrary which is understandable since all of that information was wrapped in secrecy through court confidentiality orders prior to May 20, 2009. The district court had no duty to submit that issue to the jury where the facts were undisputed.

TOLLING

Ms. Stevens also argued in the district court that the statute of limitations was effectively tolled from September 15, 2005, until November 14, 2007, based on a class action pending against NPC during that period. (Doc. 346, pp. 16-19) The facts regarding the class action were also undisputed. For that reason, as well as the fact that Novartis' jury instruction misstated the law by advising the jury that her claim was barred if she knew the name of the manufacturer within three years after learning of her injury, the court declined to give NPC's jury instruction regarding the statute of limitations. (Tr. 1782-1786)

Attached as Exh. No. 3 to plaintiff's brief in opposition to the defendant's motions for summary judgment (Doc. 346, App. 13) was a copy of the complaint in *Anderson, et al, v. Novartis Pharmaceuticals Corporation*, Case No. 3 05 0718 filed in the United States district court for the Middle District of Tennessee on September 15, 2005. It was brought pursuant to Rule 23, F.R.Civ.P. on behalf of putative class members who used Zometa (§1). It alleged that the individually

named plaintiffs were individuals who had consumed Zometa and developed ONJ (§§2-11). It alleged that NPC failed to adequately warn doctors or consumers of the drug's dangers (§20) and that there were thousands of other putative class members who had been similarly injured (§12). It alleged, as did Ms. Stevens in this case, that NPC was negligent as a result of its acts and omissions (§32).

The *Anderson* complaint was pending for 26 months until, November 14, 2007, when the district court ordered that the cases be severed and that individual amended complaints be filed. A copy of that order was attached to plaintiff's brief as Exh. No. 4 and is attached hereto as App. 14.

The United States Supreme Court has determined that a statute of limitations, which would normally bar a claim, is tolled during the pendency of a putative class action asserting substantially the same claim. *American Pipe and Construction Company v. Utah*, 414 U.S. 538 (1974); *Crown, Cork and Seal Company v. Parker*, 462 U.S. 345 (1983) The tolling will apply whether the class certification is granted or denied. *Tosti v. City of Los Angeles*, 754 F.2d 1485 (9th Cir. 1985)

In *Crown, Cork and Seal Co.*, the court held that "[t]he filing of a class action tolls the statute of limitations as to all asserted members of the class not just as to interveners" *Crown, Cork and Seal Co.*, 462 U.S. at 350 (internal quotation marks and citation omitted).

The court also explained why tolling makes sense as a matter of public policy, 462 U.S. at 352-53 (emphasis added):

Class members who do not file suit while the class action is pending cannot be accused of sleeping on their rights; Rule 23 both permits and encourages class members to rely on the named plaintiffs to press their claims. And a class complaint “notifies the defendants not only of the substantive claims being brought against them, but also of the number and generic identities of the potential plaintiffs who may participate in the judgment.” *American Pipe*, 414 U.S., at 555; see *United Airlines, Inc., v. McDonald*, 432 U.S. 385, 395 (1977). **The defendant will be aware of the need to preserve evidence and witnesses respecting the claims of all the members of the class. Tolling the statute of limitations thus creates no potential for unfair surprise, regardless of the method class members choose to enforce their rights upon denial of class certification.**

Similarly, most state courts to consider this issue (17 different jurisdictions cited) have held that the pendency of a putative class action which does not achieve class action status tolls the applicable statute of limitations for the benefit of any individual claimant who would have been a class member if the class had been certified. See *Staub v. Eastman Kodak Co.*, 726 A.2d 955, 963 (N.J. Super. Ct. App. Div. 1999) and cases cited therein.

The logic of the Supreme Court as applied in other states is sound. When a class action is pending against a defendant, it is on notice of its need to prepare for and defend claims of an identical nature. Individuals are encouraged for purposes of judicial economy to defer to the class. The public policy reasons for which statutes of limitation are established are accomplished. Therefore, in the interest of

resolution on the merits, the statute should be tolled during the pendency of the class action.

NPC failed to discuss tolling in its opening brief. It is not permitted to reserve that argument for its reply brief to which Peggy Stevens has no opportunity to respond. This court “will not address the merits of an issue presented for the first time in a reply brief.” In *re Estate Bovey*, 2006 MT 46, ¶11, 331 Mont. 254, 132 P.3d 510 (citing *Pengra v. State*, 2000 MT 291, ¶13, 302 Mont. 276, 14 P.3d 499). See also *City of Billings v. Mouat*, 2008 MT 66, ¶15, 342 Mont. 79, 180 P.3d 1121 (“M.R. App. P. 12(3) prohibits an appellant from raising new issues in a reply brief.”)

Nevertheless, the following responses are offered to those arguments made by NPC in the district court.

First, in its reply brief in support of summary judgment, it contended that tolling could not be applied cross jurisdictionally from a federal court class action to a state court individual action and cited several authorities although none from this court for that principle. (DOC. 375, pp. 9-11) There is no logic to that position. The rationale for tolling applies equally whether the original class action is filed in federal or state court. NPC received no less notice from the federal court action in Tennessee than it would have had if the action had originally been filed in Montana. The better reasoned authorities are in accord. See *Staub v. Eastman*

Kodak Co., 726 A.2d 955, 967, n. 4 (N.J. Super. Ct. App. Div. 1999); *Vaccariello v. Smith & Nephew Richards, Inc.*, 763 N.E.2d 160, 163 (Ohio 2002); *Lee v. Grand Rapids Board of Education*, 384 N.W.2d 165, 168 (Mich. App. 1986); and *Hyatt Corp. v. Occidental Fire & Cas. Co.*, 801 S.W.2d 382 (Mo. Ct. App. 1990).

NPC's second argument in the district court was that tolling did not apply because Peggy Stevens was not within the class for which certification was sought in federal district court. (Doc. 375, pp. 11-13) As is evident from the attached complaint, that was incorrect. (App. 13)

In support of that argument, NPC attached to its brief a companion but completely separate class action related to monitoring patients who did not yet have ONJ. At no time has NPC disputed that the class action relied on by Ms. Stevens was pending from September 15, 2005, until November 14, 2007. Nor can it dispute, based on the plain language of that complaint, that it related to damages for bisphosphonate-induced osteonecrosis of the jaw.

For these additional reasons, the district court properly denied NPC's motion to dismiss based on the statute of limitations and its erroneous and unsupported instruction.

II. DUTY TO WARN

STANDARD OF REVIEW

A district court's decision to instruct the jury is reviewed for an abuse of

discretion, *White v. Johnson*, 2009 MT 254, ¶23, 351 Mont. 534, 215 P.3d 11. However if the district court's decision is based on a conclusion of law, this court's review is plenary. *Jacobsen v. Allstate Ins. Co.*, 2009 MT 248, ¶50, 351, Mont. 464, 215 P.3d 649.

“[a]ll jury instructions must be read as a whole and the party assigning error to the court's instructions must show prejudice in order to prevail. Such prejudice will not be found if the jury instructions in their entirety state the applicable law of the case.” *Hall v. Big Sky Lumber, Inc.*, 261 Mont. 328, 332, 863 P.2d 389, 392 (1993) (citations omitted).

SUMMARY OF ARGUMENT

The district court correctly instructed the jury regarding NPC's duty to warn healthcare providers who were in a position to reduce the risk of harm from NPC's drug. And, the jury's application of that instruction was even further limited by the district court's verdict form.

DISCUSSION

Throughout this litigation, NPC has taken the restrictive and unreasonable position, based on its mischaracterization of Montana case law, that its duty to warn was satisfied if it provided some minimal amount of information to Dr. Judy Schmidt, the person who originally prescribed Zometa for Peggy Stevens back in 2002 even though Ms. Stevens was no longer under her care when she decided to have her tooth pulled in 2004 and Dr. Schmidt would have had no opportunity to communicate the proper precautions to her had she even known about them. That is not now and never has been the law in Montana.

Novartis cites *Hill v. Squibb and Sons, E.R.*, 181 Mont. 199, 592 P.2d 1383 (1979) and its incorrect characterization in an out-of-state text as its only authority for its argument that Montana has adopted this restrictive view of the “learned intermediary doctrine,” which would limit a drug manufacturer’s duty to communicate dangers to the physician who originally prescribed the medication no matter how far removed that physician becomes from the patient’s care and the danger about which a warning is required. However, that case never mentions the “learned intermediary doctrine.” In fact, the issues presented in this case were nowhere discussed in the *Hill* decision. The fact that it is mischaracterized as a “learned intermediary” decision by an out-of-state text is a result of a publishing company’s keynote terminology and has nothing to do with anything said by the court which issued the opinion.

In *Hill*, the allegation was that the package inserts provided by the defendant drug company did not adequately warn of its dangerous side effects. The defendant was dismissed by directed verdict when no expert testimony was offered in support of that theory. The Supreme Court agreed. It stated in dicta that a drug manufacturer has a duty to adequately warn a physician who prescribes its drugs. *Hill*, 592 P.2d at 1388. However, that was because that was the only claim made. That was not the basis for its decision. Its decision was based on the court’s conclusion that expertise is required to determine whether the warning is adequate

and none had been offered. At no time did the court discuss whether the drug manufacturer has a duty to inform treating physicians other than the prescribing physician of the dangers presented by its drug if it is known by the manufacturer that treating physicians can harm patients without that knowledge. The Restatement of Torts which has been repeatedly accepted and followed by the Montana Supreme Court² does discuss that duty. It states:

“A prescription drug or medical device is not reasonably safe due to adequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to prescribing ***and other healthcare providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings.*** (emphasis added)

Restatement 3d of Torts: Products Liability, Section 6(d)(1).

Furthermore, Comment (d)(2) to Section 6(d) provides:

“Beyond informing prescribing health-care providers, a drug or device manufacturer may have a duty under the law of negligence to use reasonable measures to supply instructions or warnings to non-prescribing health-care providers who are in positions to act on such information so as to reduce or prevent injury to patients.”

The Court’s instruction accurately explained this duty.

The Court’s instructions were especially appropriate considering the testimony of Peggy Stevens that when she had her tooth pulled all of her interaction was with the nurses and locum tenans physicians at Guardian Oncology

² Examples found @ App. 15.

and her testimony that when she decided to have her tooth pulled, it was the nurses and the locum tenans physicians whom she advised of that intention. Likewise, on page 1228 of the transcript, Joni Landes, Guardian Oncology's office manager, testified that she and the nursing staff administered Zometa, opened the packages, looked for the insert and determined whether there were precautions that should be taken. She also testified on p. 1258 that at the time Peggy Stevens had her tooth pulled there were at least two staff physicians other than Dr. Schmidt who were treating her and that Dr. Schmidt was not seeing patients at all. (Tr. 1065)

And even though the law as set forth in Restatement (Third) clearly extends NPC's duty to Ms. Stevens' oral surgeon, it is not possible that the jury could have construed the Court's instructions to permit a finding of liability for failing to warn him. The jury had to specifically find in response to question 1 of the verdict form that Novartis' negligence was based on inadequate information provided to Judy Schmidt or the professional staff at Guardian Oncology.

Nor did plaintiff's counsel argue, as suggested on p. 28 of NPC's brief, that it had that duty. The referenced remarks (with incorrect transcript citations) all relate to argument about causation. The correct reference to the record is to Tr. 1968, 1843, and 1971.

On p. 26 of its brief, NPC contends that on the two previous occasions when this court considered the Restatement (Third) of Torts, it declined to adopt it.

However, on both of those occasions it was because the Restatement (Third) provided less protection to Montana consumers, not, as in this case, because it would provide greater protection than the alternative. See *Malcolm v. Evenflo Co.*, 2009 MT 285, 352 Mont. 325, 217 P.3d 514 and *Sternhagen v. Dow Co.*, 282 Mont. 168, 176-182, 935 P.2d 1139, 1144-1147 (1997).

Nor does *In re Fosamax Prods. Liab. Litig.*, No. 1:06-MD-1789-JFK, 2010 WL 330220, at *5 (S.D.N.Y. Jan. 27, 2010) stand for the restricted view of the learned intermediary doctrine advocated by NPC. That case did not limit a drug manufacturer's duty of warning to the prescribing physician. It simply distinguished between the manufacturer's duty to a "treating" physician as opposed to the patient.

The courts in the following cases have quoted, adopted and/or explicitly followed §6(d). Some still refer to it as the "learned intermediary doctrine" even though the Restatement is a more current version. *Tyler v. Squibb*, 2010 U.S. Dist. LEXIS 40268 (D. Neb. Apr. 23, 2010) ("[t]o determine whether a manufacturer may be liable for a warning or a defect in a prescription drug case, Nebraska uses the learned intermediary doctrine in § 6(d) of the Third Restatement of Torts"); *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 764-770 (Ky. 2004) (upon certification of the issue to the Kentucky Supreme Court, the court adopted § 6(d)); *Madsen v. Am. Home Prods. Corp.*, 477 F. Supp. 2d 1025, 1034 (E.D. Mo. 2007) ("Iowa's

adoption of the Restatement (Third) of Torts analytical framework for product defect cases and the overwhelming precedent adopting the learned intermediary doctrine convinces the Court that the Iowa Supreme Court would recognize that the doctrine governs Plaintiff's failure-to-warn claims at issue"); *Tenuto v. Lederle Lab.*, 181 Misc. 2d 367, 377 (N.Y. Sup. Ct. 1999) (quoting and following this section).

The district court properly instructed the jury regarding the manufacturer's duty to warn healthcare providers. Restricting its instruction to Judy Schmidt, who was no longer responsible for her care, would have ignored the factual record and provided no meaningful protection to people injured by manufacturer's negligent conduct. However, even if the instruction was incorrect, it was harmless based on the court's verdict form. (*supra*, p. 7)

III. PRIOR PLEADINGS, EXPERT DISCLOSURE AND DISCOVERY RESPONSES

STANDARD OF REVIEW

This court reviews a district court's evidentiary ruling for an abuse of discretion. *Malcolm v. Evenflo Co., Inc.*, 2009 MT 285, ¶29, 352 Mont. 325, 217 P.3d 514. A district court possesses broad discretion to determine the admissibility of evidence and it will abuse its discretion only "when it acts arbitrarily without conscientious judgment or so exceeds the bounds of reason as to work a substantial injustice" *Malcolm*, ¶29 (citation omitted).

SUMMARY OF ARGUMENT

The district court did not err by refusing to admit prior pleadings stating an alternative theory of recovery, unsworn written summaries of expert opinions, or unverified interrogatory answers prepared by plaintiff's attorneys and based on opinion and legal theory, since they were neither judicial admissions nor met the requirements of judicial estoppel – the only reasons offered for their admission.

DISCUSSION

The only reasons offered for the admission of these out-of-court hearsay documents was that they were prior judicial admissions and that plaintiff was judicially estopped from denying their contents. (Doc. 302, p. 1)

All of the documents were prepared by plaintiff's attorney based on what he believed to be true prior to discovery which disclosed the full extent to which NPC had concealed evidence of Zometa's risks and misled the public and medical profession. None of the documents were prepared by or signed by Peggy Stevens. Any fair consideration of the documents' value would have required that plaintiff's attorney testify, explain what he knew at the time the documents were prepared, what he had learned since, why they were not inconsistent, and why they had nothing to do with the merits of the case against NPC.

Furthermore, none of the documents were judicial admissions and the doctrine of judicial estoppel was inapplicable. Therefore, no legitimate basis for their admission was suggested to the district court.

The documents were never offered as an exception to the hearsay rule pursuant to Rule 801. That argument has been made for the first time on appeal and was waived. However, even if an exception to the hearsay rule, the documents would still have been irrelevant and had no probative value compared to their misleading effect.

In essence, Novartis wanted to offer prior pleadings, expert witness disclosures, and an attorney affidavit to prove that Dr. Judy Schmidt, rather than Novartis, was negligent. However, its motion to amend to blame Dr. Schmidt had been denied and proof of medical negligence requires expert medical opinion testimony which establishes the applicable standard of care and a departure from that standard. *B.J. v. Schultz*, 2009 MT 245, ¶ 13, 351 Mont. 436, 214 P.3d 772, (citing *Butler v. Domin*, 2000 MT 312, ¶ 21, 302 Mont. 452, 15 P.3d 1189). An attorney cannot give an opinion about the standard for medical care and neither an expression of an opinion nor a party's superseded legal theory can be a judicial admission.

In order “[f]or a judicial admission to be binding on a party, the admission must be one of fact rather than a conclusion of law or the expression of an opinion.” *DeMars v. Carlstrom*, 285 Mont. 334, 338, 948 P.2d 246, 248-49 (1997). See also, *Bitterroot Intl. Sys. v. Western Star Trucks, Inc.*, 2007 MT 48, ¶

43, 336 Mont. 145, 153 P.3d 627 (finding only factual assertions regarding when the defendant received certain documents qualified as judicial admissions).

Nor does a judicial admission include a party's superseded legal theory. "[A] judicial admission applies to facts, not to legal theories or positions." *Stanley L. and Carol M. Watkins Trust v. Lacosta*, 2004 MT 144, ¶ 34, 321 Mont. 432, 92 P.3d 620.

Various courts have determined that allegations in an original complaint are not judicial admissions. See *Gary v. United States*, 67 Fed. Cl. 202, 210 (Fed. Cl. 2005); and *Joseph Huber Brewing Co. v. Pamado, Inc.*, 2006 U.S. Dist. LEXIS 67174 (M.D. Ill. Sept. 5, 2006). Additionally, an expert's testimony cannot constitute a judicial admission because he or she is not a party representative. *Shepler v. Love*, 2001 Ohio App. LEXIS 4101 (Ohio Ct. App., Huron County Sept. 14, 2001).

Finally, the affidavit of an attorney for a party is not admissible because he or she cannot be a witness at trial. See Rule 3.7, M.R.Prof.Cond.; *Vestre v. Lambert*, 249 Mont. 455, 463, 817 P.2d 219, 223 (1991); See also, *United States v. Real Property in Mecklenburg County*, 814 F. Supp. 468, 472, fn. 6 (W.D.N.C. 1993); *McIntosh v. Southwestern Truck Sales*, 304 Ark. 224, 225 (1990).

Nor does judicial estoppel apply to positions taken in the same case. It applies to an inconsistent position taken in "a subsequent action or proceeding."

Kauffman-Harmon v. Kauffman, 2001 MT 238, ¶ 15, 307 Mont. 45, ¶ 15, 36 P.3d 408.

Nor could Novartis meet 3 out of the 4 elements for the application of judicial estoppel. It could not show that 1) Peggy Stevens was aware of the relevant fact when prior pleadings were filed; 2) that her original position was inconsistent with her claim against NPC; (In Montana, a person's injury can be caused by more than one negligent party. See *Ganz v. United States Cycling Fed'n*, 273 Mont. 360, 368, 903 P.2d 212, 216 (1995) and *Onstead v. Payless Shoe Source*, 2000 MT 230, ¶ 45, 301 Mont. 259, 9 P.3d 38.) or 3) that NPC, in any way, relied on her pleadings. All were necessary. See *Vogel v. Intercontinental Truck Body, Inc.*, 2006 MT 13, P10, 332 Mont. 322, 137 P.3d 573.

In addition, in order to have an estoppel effect, the parties' previous representations must be "an unequivocal statement of fact" and not a statement made in purposes of advancing "a legal position." *Stanley L. and Carolyn M. Watkins Trust v. Lacosta*, 2004 MT 144, ¶34, 321 Mont. 432, 92 P.3d 620. See also, *City of Whitefish v. Troy Town Pump*, 2001 MT 58, ¶15, 304 Mont. 346, 21 P.3d 1026; *Elk Park Ranch, Inc. v. Park County*, 282 Mont. 154, 935 P.2d 1131 (1997)(both distinguishing factual from legal representations for purposes of estoppel).

Even if considered, Rule 801(d)(2) operates only to remove party-admissions from the definition of hearsay, it does not address the broader question of admissibility. Party-admissions must still satisfy the admissibility requirements of Rules 402 and 403 M.R.Evid. See *Aliotta v. Amtrak*, 315 F.3d 756, 763 (7th Cir. 203); *United States v. Kattar*, 840 F.2d 118, 131 (1st Cir. Mass. 1988); and *Vincent v. Louis Marx & Co.*, 874 F.2d 36, 41 (1st Cir. Mass. 1989) where prior inconsistent statements were excluded because the prejudicial impact exceeded probative value.

And, “in contrast to pleadings from prior lawsuits which are admitted by some courts only when they show inconsistency, hypothetical or alternative pleadings tend to be excluded when they are inconsistent with positions taken at trial” because a plaintiff is entitled to plead alternatively and hypothetically regardless of consistency. Sherman J. Clark, *To Thine Own Self Be True: Enforcing Candor in Pleading Through the Party Admissions Doctrine*, 49 Hastings L.J. 565, 570-71 (March 1998); see also, 4 Louisell and Mueller, Federal Evidence § 425, 306; *McCormick on Evidence* § 265, 781-82; and 30B Wright & Miller, Federal Practice and Procedure: Evidence, § 7026 (2000). Indeed, as stated by the Ninth Circuit:

Therefore, as the Fifth Circuit has ruled, “one of two inconsistent pleas cannot be used as evidence in the trial of the other” because a contrary rule “would place a litigant at his peril in exercising the

liberal pleading . . . provisions of the Federal Rules.” *Continental Ins. Co. v. Sherman*, 439 F.2d 1294, 1298-99 (5th Cir. 1971).

Oki America, Inc. v. Microtech Intl., Inc., 872 F.2d 312, 313-314 (9th Cir. Cal. 1989) (internal citations omitted).

See also, *Continental Ins. Co. v. Sherman*, 439 F.2d 1294, 198 (5th Cir. Fla. 1971); *Svege v. Mercedes Benz Credit Corp.*, 329 F. Supp. 2d 285, 287 (D. Conn. 2004); and *Garman v. Griffin*, 666 F.2d 1156, 1158 (8th Cir. Mo. 1981).

On p. 30, NPC gives the misimpression that the jury was not informed of Peggy Stevens’ prior complaint against Judy Schmidt. It is true that the district court held that fact inadmissible. However, that ruling did not prevent NPC from ignoring the court’s decision, asking the question, and getting the answer that it sought. (Tr. 1006)

On pp. 31 and 32 of its brief, NPC cites numerous authorities for the admission of prior pleadings. However, every case cited dealt with a party’s factual representations and subsequent effort to state the opposite. None of those cases involve a party’s legal theories, opinions, or alternate theories of liability which are the issue in this case, and, therefore, none are applicable.

IV. LATE AMENDMENT TO ASSERT APPORTIONMENT DEFENSE

STANDARD OF REVIEW

District court’s denial of a Rule 15(a) M.R.Civ.P. motion to amend is reviewed for an abuse of discretion. *Deschamps v. Treasure State Trailer Court*,

SUMMARY OF ARGUMENT

The district court did not abuse its discretion when, on the eve of trial, and after its repeated refusal to answer discovery regarding its basis for blaming any third party, the district court denied NPC's motion to amend its answers to blame third parties after they had been dismissed from this action.

DISCUSSION

NPC refused to respond to written discovery submitted on March 16, 2009, requesting information about whether it blamed any third party for Peggy Stevens' injuries. (App. 16, pp. 13-14) It refused to do so again in response to discovery submitted on May 6, 2009, which requested information about its affirmative defenses. (App. 17, pp. 4-5) It still hadn't answered those requests for information by June when notified of plaintiff's intent to settle with and dismiss Dr. Schmidt and Guardian Oncology. Nor had it done so by July 8, 2009, when both defendants were dismissed.

On August 4, 2009, after those defendants were dismissed and no longer had a reason to incur the expense of defending themselves, and without having identified any expert to establish that Dr. Schmidt or her clinic had acted negligently, NPC moved to amend its answer to blame them and asked for contribution pursuant to §27-1-703(6)(f) MCA. However, to allow the amendment after Peggy Stevens chose to release those defendants based, in part, on the assumption that NPC had no basis in fact for blaming them and after they no

longer had any incentive to defend themselves, would have been prejudicial to Ms. Stevens. Directly on point is *Eisenmenger v. Ethicon*, 264 Mont. 393, 871 P.2d 1313 (1994).

§27-1-703(6)(f) takes possible prejudice based on party's unreasonable delay into consideration when it requires that "a defendant who gains actual knowledge of a settled or released person after the filing of defendant's answer may plead the defense of settlement or release **with reasonable promptness**, as determined by the trial court, . . . " Here, where defendant was notified of the settlement on June 12 and waited until August 4 to file its motion, when the case was set for trial in October, the district court correctly concluded that it had not acted with reasonable promptness. (App. 18, p. 6)

Nor did NPC comply with §27-1-703(6)(e) MCA which requires that "a defendant who alleges that a person released by the claimant or with whom the claimant has settled is at fault in the matter has the burden of proving: (i) the negligence of the person who the claimant has released or with whom the claimant has settled." Proof of medical negligence requires expert opinion testimony. *B.J. v. Schultz*, 2009 MT 245, ¶13, 351 Mont. 436 P.3rd (citing *Butler v. Domin*, 2000 MT 312, ¶21, 302 Mont. 452, 15 P.3rd 1189.) At no time did Novartis identify expert witnesses who would testify that the standard of care applicable to Dr. Judy Schmidt or Guardian Oncology was breached.

A district court “is justified in denying a motion [to amend] for an apparent reason such as undue delay, bad faith or dilatory motive on the part of the movant, . . . undue prejudice to the opposing party by allowance of the amendment, futility of the amendment, etc.” *Bitterroot Inter. Sys. v. West. Star Trucks*, 2007 MT 48, ¶ 50, 336 Mont. 145, 153 P.3d 627.

Untimely cross claims have been disallowed in *Equal Rights Ctr. v. Archstone Smith Trust*, 603 F. Supp. 2d 814, 826 (D. Md. 2009); *Ha-Lo Indus. v. Kelly (In re Ha-Lo Indus.)*, 2004 Bankr. LEXIS 8 (Bankr. N.D. Ill. Jan. 5, 2004); *Campanella v. Raymark Industries, Inc.*, 1990 Pa. Dist. & Cnty. Dec. LEXIS 227 (Pa. C.P. 1990); *Aalmuhammed v. Kesten*, 2000 U.S. Dist. LEXIS 8646 (S.D.N.Y. June 20, 2000); and *Travelers Prop. Cas. Co. of Am. v. Liberty Surplus Ins. Corp.*, 2009 U.S. Dist. LEXIS 36112, 4 5 (C.D. Cal. Apr. 17, 2009).

V. CAUSATION

STANDARD OF REVIEW

The court’s scope of review of a jury’s verdict is limited to “whether there is substantial credible evidence in the record supporting the jury’s verdict.” *Avanta Fed. Credit Union v. Shupak*, 2009 MT 458, ¶21, 354 Mont. 372, 223 P.3d 863 (citation omitted).

SUMMARY OF ARGUMENT

Peggy Stevens presented evidence in abundance relating her osteonecrosis of the jaw to NPC’s negligent failure to warn her healthcare

providers and the tooth extraction she underwent as a result.

DISCUSSION

Dr. Eugene Morris is the oral surgeon who removed Peggy's tooth on September 27, 2004. (Exh. No. 277, Tr. 520-521) He did not advise her at that time that she was at risk for ONJ from removal of the tooth because he was unaware of that fact in 2004. (Tr. 523) He first learned of the relationship between Zometa and ONJ from professional literature in 2006. (Tr. 526-527)

Based on his current standard of practice, if he knew a person was being treated with Zometa, he would take additional precautions and first attempt a root canal to try to stabilize the tooth in the jaw without traumatizing the tissue or any bony structures. (Tr. 528, 529) If he had known in 2004 what he knows now, he would not have removed Peggy Stevens' tooth. (Tr. 529)

He testified that crown lengthening was also an option for Peggy, as well as root canal therapy. (Tr. 548) He testified that there are various degrees of invasive procedure including that which involves only soft tissue without injuring the bone. (Tr. 562, 563) The most invasive procedure available to Peggy was removal of her tooth. (Tr. 563) Crown lengthening is not highly invasive. (Tr. 548) Dr. Vincent Meng, her dentist, explained that a root canal is a soft tissue procedure which does not even involve the bone. (Tr. 562, 563)

Dr. Marx also testified that only dental procedures invasive to the bone

present a risk of ONJ and that a procedure such as a root canal is perfectly safe because it does not involve bone. (Tr. 806, 807) Even NPC's own June 2004 "white paper" states that endodontic "root canal therapy" is preferable to tooth extractions where possible. (Tr. 830)

Dr. Marx, after reviewing her records testified unequivocally that the tooth extraction began the whole process because it traumatized the bone, the bone could not cope with the trauma because it was missing osteoclast, and it ended up dying. (Tr. 795) Dr. Meng agreed. (Tr. 593, 594)

The evidence of causation could not have been clearer.

MMLP Pleading

When NPC's attorneys, after asking repeatedly, could not get Dr. Morris to agree that he had no alternative to a tooth extraction, it sought to impeach him with a confidential document prepared by his attorneys and filed with the Montana Medical-Legal Panel. It laid no foundation to show that Dr. Morris had anything to do with the document's preparation or had ever even read it. Nor could his attorney have been examined regarding the basis for the statements which it included. Therefore, reference to the document would have been highly misleading to the jury and was properly excluded for all the reasons discussed in the previous section regarding prior pleadings.

In addition, MMLP documents are inadmissible because they are

confidential. §27-6-703 MCA which applies to MMLP proceedings provides the following:

“The directors shall maintain records of all proceedings before the panel, which must include the nature of the act or omissions complained of, a brief summary of the evidence expressed, the decision of the panel . . . any records which may identify any party to the proceedings may not be made public and are not subject to subpoena but are to be used solely for the purpose of compiling statistical data and facilitating ongoing studies of medical malpractice in Montana.”

NPC subpoenaed the document from the files of Dr. Schmidt. It was produced at her second deposition which was defended on Plaintiff’s behalf by an out-of-state attorney unfamiliar with the confidentiality provision.

Nor is this court’s decision in *Linder v. Smith*, 193 Mont. 20, 30, 629 P.2d 1187, 1192 (1991) cited on p. 37 of NPC’s brief, applicable to pleadings before the MMLP. It relates to inconsistent testimony given at the MMLP. Pleadings do not embody the testimony of any witness. In fact, §27-6-306(1) and (2) MCA make clear that the answer is an informal document submitted by a party’s attorney who, as previously explained, could not have been called in this proceeding to explain his answer or the source of his information.

VI. EVIDENCE OF POST 9/27/04 CHANGES IN GUARDIAN ONCOLOGY’S OFFICE PROTOCOL

STANDARD OF REVIEW (See p. 34)

SUMMARY OF ARGUMENT

After NPC's repeated arguments that adequate warnings about the risk of its dangerous drug would not have made any difference because Peggy Stevens' healthcare providers at Guardian Oncology would not have advised her about the risk anyway, it was permissible and necessary to demonstrate that once they had knowledge of the risk, their office procedure was changed to provide advice to their patients.

DISCUSSION

NPC contended in its answer (Doc. 141, ¶10), its motion for summary judgment based on warnings (Doc. 309, pp. 1 and 2), the pre-trial order (DOC. 384, p. 10), and in its opening statement (Tr. 433-434) that adequate warnings would not have made any difference because they would not have been passed on to Peggy Stevens in any event. However, that was not true as was clearly established by the testimony of Joni Landes, Dr. Schmidt's office manager. She testified that as a result of her own research, she learned from an Oncology Nursing Society bulletin in February of 2005 of the relationship between Zometa and ONJ. (Tr. 1222) She and her colleagues had been unaware of that fact before. Therefore, they changed their standard of care regarding administration of the drug at that point. (Tr. 1222, 1223) There was no mention by Joni Landes of any subsequent warning given by NPC. Nor was the document she received from the society ever admitted or shown to the jury.

Ms. Landes testified that as a result of the information received from the society, office protocol had been changed to include advice about the relationship

of Zometa, tooth extractions and ONJ. (Tr. 1231) Dental screening is now required prior to treatment with Zometa, additional screenings are required every six months while receiving it (Tr. 1231-1232), and dental appointments are actually made for patients. (Tr. 1232) Notice was also sent to dentists and oral surgeons. (Tr. 1235, 1236)

Prior to the information she received on February '05 from the nursing society, which was the first clear indication of a risk, there was no office protocol for advising patients. To her knowledge, no one in the office was even aware of it. (Tr. 1234)

This evidence did not involve subsequent measures by NPC, and Rule 407 does not apply to subsequent remedial measures taken by a non-party (Guardian Oncology) because admission of such evidence will not expose that non-party to liability, and therefore will not discourage the non-party from taking the remedial measures in the first place. *Pau v. Yosemite Park*, 928 F.2d 880, 888 (9th Cir. 1991); *Diehl v. Blaw-Knox*, 360 F.3d 426, 430 (3d Cir. Pa. 2004); *Millennium Partners, L.P. v. Colmar Storage, LLC*, 494 F.3d 1293, 1302-1303 (11th Cir. Fla. 2007); *O'Dell v. Hercules, Inc.*, 904 F.2d 1194, 1204 (8th Cir. 1990); *Raymond v. Raymond Corp.*, 938 F.2d 1518, 1523-24 (1st Cir. 1991); *Dixon v. International Harvester*, 754 F.2d 573, 583 (5th Cir. 1985); *Mehojah v. Drummond*, 56 F.3d 1213, 1215 (10th Cir. 1995); *TLT-Babcock, Inc. v. Emerson Elec. Co.*, 33 F.3d

397, 400 (4th Cir. 1994); *Lolie v. Ohio Brass Co.*, 502 F.2d 741, 744 (7th Cir. 1974) (per curiam); *see generally* 2 Weinstein's Federal Evidence § 407.05[2] (Joseph M. McLaughlin ed., 2d ed. 2003).

Furthermore, the change in Dr. Schmidt's office procedure was not admitted to establish liability which is the only thing prohibited by Rule 407. It was admitted to establish that an adequate warning to that office by NPC would have been provided to Peggy Stevens and that its failure to do so resulted in her tooth extraction. It would have been admissible for that purpose even if it had been NPC's remedial measure – which it wasn't. *See Wetherill v. University of Chicago*, 565 F. Supp. 1553, 1558 (N.D. Ill. 1983); *Baroldy v. Ortho Pharmaceutical Corp.*, 760 P.2d 574, 586-87 (Ariz. Ct. App. 1988); and *Bastoe v. Sterling Drug, Inc.*, 1989 U.S. Dist. LEXIS 18095 (S.D. Miss. Nov. 7, 1989).

Likewise, in *Rieger v. Coldwell*, 254 Mont. 507, 512, 839 P.2d 157, 1259-60 (1992), this court held that the plaintiff should have been permitted to introduce evidence of subsequent repairs to light fixtures other than the one involved in the accident in order to refute testimony that defective sheetrock at the scene of the accident was its sole cause.

CROSS APPEAL

I. SECOND AMENDED COMPLAINT

STANDARD OF REVIEW

(See p. 40)

SUMMARY OF ARGUMENT

The district court erred when it refused to permit Peggy Stevens to file a second amended complaint. The Montana Rules of Civil Procedure provide for liberal amendment of pleadings where justice so requires and prejudice does not result. Both criteria were satisfied in this case.

DISCUSSION

On September 21, 2009, Peggy Stevens petitioned this court for supervisory control and asked that it reverse the order of the district court denying her motion to amend her complaint to state a claim for punitive damages and to expand the population of treating physicians to whom a duty to warn was owed by NPC. That petition is attached hereto as App. 19. The arguments found therein are incorporated by reference and will not be repeated in their entirety.

The allegations were not new to Novartis. They had been made by hundreds of other parties as far back as the class action filed in 2005.

The allegations do not require additional time by NPC to defend because they arose out of the same operative facts which served as the basis for NPC's liability. When a plaintiff is simply adding an additional theory of liability based on the same operative facts, this court has held that it would be an abuse of

discretion not to allow the plaintiff to amend. *Sooy v. Petrolane Steel Gas, Inc.*, 218 Mont. 418, 421, 708 P.2d 1014, 1016 (1985) That is what happened in this case.

By a 4-2 vote, this court denied supervisory control without comment on the merits of the district court's denial of the motion to amend and without prejudice to re-raise the issue on appeal. (App. 20, p.2)

Peggy Stevens now avails herself of this opportunity to have that denial reviewed on the merits.

II. DISMISSAL OF PATRICK DOYLE

STANDARD OF REVIEW (See p. 15)

SUMMARY OF ARGUMENT

The district court erred when it concluded that because Patrick Doyle acted within the scope of his employment, he had no personal liability for his own wrongful conduct. In Montana, everyone is liable for his own wrongful conduct.

DISCUSSION

The district held that Peggy Stevens did not allege that Doyle had independently done anything wrong or acted other than within the scope of his employment and that, therefore, pursuant to *Crane Creek Ranch, Inc. v. Cresap*, 2004 MT 351, ¶13, 324 Mont. 366, 103 P.3rd 535, Doyle should be dismissed.

The court erred for two reasons. First, the complaint did allege that Doyle

was independently negligent. Second, employees are not immune from liability for their own negligent acts simply because committed during the course of their employment.

In her complaint, Ms. Stevens alleged that either Dr. Schmidt and her office had information about ONJ and did not communicate it to her, or Doyle **and** Novartis Pharmaceutical Corporation did not advise Schmidt of the risk in a timely fashion and were negligent for failing to do so. (Complaint ¶20) The complaint was clearly stated to provide for the eventuality that information had been given to Doyle to pass along to Schmidt, but that he had not delivered it. (e.g. the “white paper”) Doyle testified at his deposition that he was unaware how soon after he received the “white paper” he delivered it to Judy Schmidt or her office.

The liability of an agent or employee for his own negligent conduct is clearly established by statute in Montana pursuant to § 28-10-702(3) MCA which provides in relevant part as follows:

“One who assumes to act as an agent is responsible to third persons as a principal for his acts in the course of his agency in any of the following cases and in no other:

...

(3) When his acts are wrongful in their nature.”

In other words, “An agent is jointly and separately liable with his principal to third parties for wrongful acts committed in the course of his agency.” *Crystal*

Springs Trout Co. v. First State Bank, 225 Mont. 122, 129 732 P. 2d 819, 823 (1987).

However, if the district court's judgment is otherwise affirmed in this case, it is not necessary that the court consider this issue.

III. OFFSET FOR FUTURE SOCIAL SECURITY PAYMENTS

STANDARD OF REVIEW

(See p. 15)

SUMMARY OF ARGUMENT

The district court erred by offsetting disability and speculative future payments against Peggy Stevens' award because it cannot be determined from the general verdict how much was attributed to lost income and the language of Montana's Collateral Source Statute does not contemplate offset for potential future benefits.

DISCUSSION

Disability payments cannot be offset because the general verdict makes it impossible to determine if these items of damage were included in the verdict.

§27-1-307, MCA defines a "collateral source" as "a payment for something that is later included in a tort award." §27-1-308 limits offsets to items specifically defined as collateral sources in §27-1-307. Since these statutes limit a party's remedy, they must be strictly construed. *Schuff v. A.T. Klemens & Son*, 2000 MT 357, ¶115, 303 Mont. 3274, 16 P.3d 1002. Therefore, before there can be an offset, the defendant must prove that the "payment" for disability benefits to Peggy

Stevens was for wage loss “included” in the jury’s award.

In *Busta v. Columbus Hosp. Corp.*, 276 Mont. 342, 196 P.2d 122 (1996), the Montana Supreme Court disallowed any offsets because the general verdict precluded any way for the Court to determine whether the type of past benefits that the defendant wanted to offset were included in the jury’s verdict.

Here, as in *Busta*, the jury was instructed that its damages could include not only economic losses, but also general damages for pain and suffering, loss of established course of life, emotional distress, and other general damages. On the verdict form, the answer to question number three states only a total damage amount of \$3.2 million. It does not allocate the damages to items that may be subject to collateral source offset. Therefore, the court had no basis on which to apply an offset for disability benefits and the result must be the same as in *Busta*. See also *Tucker v. Farmers Ins. Exchange*, 2009 MT 247, 351 Mont. 448, 215 P.3d 1.

In addition, § 27-1-307 MCA limits the definition of collateral sources to “a payment for something that is **later** included in a tort award and that is made to or for the benefit of a plaintiff.” Courts interpreting collateral source statutes with similar language have repeatedly held that a defendant cannot offset potential future benefits from a jury verdict. *Grell v. Bank of America Corp.*, 2007 WL 1362728 (M.D. Fla. 2007); *White v. Westlund*, 624 So.2d 1148 (Fla. App. 1993);

Jeep Corporation v. Walker, 528 So.2d 1203 (Fla. App. 1988); *Swamy v. Hodges*, 583 So.2d 1095 (Fla. App. 1991).

Based on similar language, the Florida Supreme Court, in *Allstate Ins. Co. v. Rudnick*, 761 So.2d 289, 292 (Fla. 2000), held that future medical benefits could not be offset.

This rationale also applies to future Social Security disability benefits. In *Swamy*, the court allowed a setoff for past Social Security disability benefits, but denied any setoffs for future Social Security benefits. *Swamy*, 583 So.2d at 1096-97. Under Montana law, which offsets only benefits which are “later” included in an award, the district court should have done likewise.

CONCLUSION

For these reasons, Peggy Stevens asks that the Court affirm the jury’s verdict, reverse in part the District Court’s offset, and remand for trial on the issue of punitive damages.

DATED this 1st day of June, 2010.

TRIEWEILER LAW FIRM


Terry N. Trieweiler

CERTIFICATE OF SERVICE

This is to certify that on the 1st day of June, 2010, a true and exact copy of the foregoing document was served on the Appellant by mailing a copy, postage pre-paid to:

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CERTIFICATE OF COMPLIANCE

Pursuant to Rule 11 of the Montana Rules of Appellate Procedure, I certify that the Appellee's Brief is printed with a proportionately spaced Times New Roman text typeface of 14 points; is double spaced; and the word count calculated by Microsoft Office Word 2003, is 12,484 words, including all text, excluding table of contents, table of citations, certificate of service and certificate of compliance.

Dated this 1st day of June, 2010.



Karen R. Weaver